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**LICOX Brain Oxygen Monitoring System,
CMP® Monitor and IMC® Systems**

K002765

510 (K) SUMMARY

Submitter's name and address:

Integra NeuroSciences
5955 Pacific Center Blvd.
San Diego, CA 92121

Contact person and telephone number:

Nancy A. Mathewson, Esq.
Director, Regulatory Affairs
(858) 455-1115

Date summary was prepared:

November 2, 2000

Name of the device:

Proprietary Name:	LICOX Brain Oxygen Monitoring System, CMP® Monitor and IMC® Systems
Common Name:	Brain Oxygen Monitoring Device
Classification Name:	Intracranial Pressure Monitoring Device, 21 CFR 882.1620, 84GWM
Classification Panel:	Neurology Device Panel

Substantial Equivalence:

The LICOX Brain Oxygen Monitoring System is substantially equivalent in function and intended use to the Neurotrend™ Cerebral Tissue Monitoring System (K980308), as well as the Paratrend 7™ Intravascular Blood Gas Monitoring System (K953893).

Device Description:

The LICOX Brain Oxygen Pressure Monitoring System (LICOX System) directly measures Partial Pressure of Oxygen (pO_2) in the brain. It consists of Oxygen sensing catheters, the LICOX CMP Monitor, and cranial access accessories. The LICOX System is utilized for continuous monitoring of brain Oxygen Partial

Pressure (pO_2). The LICOX System can also utilize brain temperature information for temperature compensation of the pO_2 value. A separate temperature probe is provided as part of the LICOX System.

The following is a list of products covered by this submission, grouped into the following categories: Disposables, CMP Monitor and Monitor Accessories. The list does not include minor accessories such as cables and power supplies, nor convenience kits, which are combinations of items listed below.

LICOX Brain Oxygen Monitoring System

Disposables	CC1.SB	Oxygen Catheter (0.8mm dia.)
	IM1	Introducer Kit with Bolt, for use with CC1.SB Oxygen Catheter
	IM2	Introducer Kit, two way, for CC1.SB & C8B Oxygen Catheter
	IM3	Introducer Kit, three way, for CC1.SB, Oxygen Catheter C8B Temperature Catheter and ICP Catheter
	C8B	Temperature Catheter
	CC1	Oxygen Catheter (0.5mm dia.)
	II1	Introducer Kit with Bolt, for use with CC1 Oxygen Catheter
	C8	Temp Catheter for II1 introducer
CMP Monitor	AC3.1	Monitor kit (includes power supply, cables etc.)
Monitor Accessories	LML (D1)	Analog interface device, for connection to patient bedside monitor

Statement of Intended Use:

The LICOX Brain Oxygen Monitoring System measures intracranial oxygen and temperature and is intended as an adjunct monitor of trends of these parameters, indicating the perfusion status of cerebral tissue local to sensor placement. LICOX System values are relative within an individual, and should not be used as the sole basis for decisions as to diagnosis or therapy. It is intended to provide data additional to that obtained by current clinical practice in cases where hypoxia or ischemia are a concern.

Comparison of technological characteristics to the predicate device:

Indications	The LICOX Brain Oxygen Monitoring System measures intracranial oxygen and temperature and is intended as an adjunct monitor of trends of these parameters, indicating the perfusion status of cerebral tissue local to sensor placement. LICOX System values are relative within an individual, and should not be used as the sole basis for decisions as to diagnosis or therapy. It is intended to provide data additional to that obtained by current clinical practice in cases where hypoxia or ischemia are a concern.	Measures intracranial oxygen, carbon dioxide, pH and temperature and is intended as an adjunct monitor of trends in these parameters, indicating the perfusion and metabolic acidosis/alkalosis status of cerebral tissue local to sensor placement. Because the Neurotrend values are relative within an individual, the Neurotrend should not be used as the sole basis for decisions as to diagnosis or therapy. It is intended to provide data additional to that obtained by current clinical practice in cases where hypoxia/ischaemia is a concern.	Use of the Paratrend 7 system is indicated where continuous monitoring of blood gases is important in the management of the critically ill adult patient. The Paratrend 7 Intravascular Sensor is inserted via an arterial catheter into the peripheral artery (e.g. radial) to provide continuous arterial blood gas data while permitting the simultaneous monitoring of blood pressure via an external transducer.
Anatomical Site	Brain parenchyma	Brain parenchyma	Radial artery
Target Population	Head trauma, craniotomy, with possible hypoxia or ischemia.	Head trauma, craniotomy, with possible hypoxia or ischemia.	Adult patients requiring blood gas monitoring

	LICOX CMP Monitor	Neurotrend Sensor Monitor	Paratrend 7 Monitor MPM7001
Operation	Microprocessor	Microprocessor	Microprocessor
Screen	Alpha-numeric	Alpha-numeric and graphical	Alpha-numeric and graphical
Monitoring	Continuous	Continuous	Continuous
Power Source	A/C wall outlet	A/C wall outlet	A/C wall outlet
Power Supply	Custom A/C-D/C Supply	Custom A/C-D/C Supply	Custom A/C-D/C Supply
Data output	Serial and Analog	Serial	Serial
Dimensions	34 cm x 32 cm x 8.5 cm	50 cm x 30 cm x 21.5 cm	50 cm x 30 cm x 21.5 cm
Weight	4.2 kg	11.4 kg	11.4 kg
Case material	Plastic	Plastic	Plastic
Operating Temperature	+10°C to +40°C	+10°C to +35°C	+10°C to +35°C
	LICOX Sensor	**Neurotrend Sensor**	**Paratrend 7 Sensor**
Parameters	Brain pO_2 Temperature sensor	Brain pO_2, temperature, pH, pCO_2	Blood pO_2, temperature, pH, pCO_2
Sterility	Sterile	Sterile	Sterile
Single-use	Yes	Yes	Yes
Monitoring duration	5days	3days	"not longer than necessary"
Tissue contacting material	Polyethylene	Polyethylene	Polyethylene
O_2 Sensing technology	Clark Cell	Fiber Optic	Clark Cell
Outside diameter	CC1: 0.5 mm CC1.SB: 0.8 mm	<0.5 mm	<0.5 mm
Patient Access	Introducer and Bolt Kit	A suitable intracranial access device	Arterial Introducer
Calibration	Smart Card calibrated to each oxygen sensor during manufacture, Smart Card read by monitor at time of use	Calibration system using a tonometer, calibration gases, and calibration chamber. Calibration performed at time of use	Calibration system using a tonometer, calibration gases, and calibration chamber. Calibration performed at time of use.
In Vitro Accuracy, pO_2	±2.0mmHg (0-20 mm Hg) ±10% (21 mm Hg-50 mm Hg) ±13% > 51 mm Hg	±3.5 mm Hg (10-60 mm Hg) ±10% (60-110 mm Hg)	±5% < 120 mm Hg ±10% ≥120 mm Hg

Temperature Sensing Technology	Thermocouple	Thermocouple	Thermocouple
In Vitro Accuracy, Temperature	±0.2°C	±0.3°C	±0.2°C

Safety

Biocompatibility studies were conducted per FDA G95-1 and ISO 10993 and have demonstrated that the materials used to manufacture the LICOX oxygen sensing catheter, temperature probe, probe introducer and bolt are safe for their intended use.

In addition, the LICOX Brain Oxygen Monitoring System was subjected to extensive performance testing. Results of the testing showed that the catheter design was technically sound and the product safe for its intended use.

The LICOX Brain Oxygen Monitoring System manufacturing process complies with the United States Food and Drug Administration and European Standards for the manufacturing of medical devices.

Conclusion:
Management of the neurological recovery of patients who suffer a traumatic brain injury or undergo brain surgery may be aided by the use of monitoring systems such as the LICOX Brain Oxygen Monitoring System, CMP® Monitor and IMC System®. When used in conjunction with the existing armamentarium, direct monitoring of the Partial Pressure of Oxygen in brain provides the clinician with an additional significant parameter that can be used to avoid secondary insult and improve recovery.

The system has been shown to be effective in measuring brain oxygen in numerous clinical studies. In addition, the system has been approved for use in the European Union.

The LICOX Brain Oxygen Monitoring System, CMP® Monitor and IMC Systems® are substantially equivalent to the predicate devices delineated in the submission and the requirements for a Premarket Notification 510(k) as defined in 21 CFR, Part 807.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 4 2000

Ms. Nancy A. Mathewson, Esq.
Manager, Regulatory Affairs
Integra Neurosciences
5955 Pacific Center Boulevard
San Diego, California 92121

Re: K002765
Trade Name: LICOX Brain Oxygen Monitoring System,
CMP® Monitor and IMC® Systems
Regulatory Class: II
Product Code: GWM
Dated: September 1, 2000
Received: September 5, 2000

Dear Ms. Mathewson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Confidential

Indications for Use Statement

510(k) Number K002765

Device Name LICOX Brain Oxygen Monitoring System, CMP® Monitor and IMC® Systems

Indications for Use

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PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801. 109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002765